

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

HARVEY H. JAY,

Plaintiff,

v.

SPECTRUM BRANDS HOLDINGS, INC.,
SPECTRUM BRANDS, INC., and SHASER,
INC.,

Defendants.

C.A. No. 1:13-cv-8137-LTS-DCF

**PLAINTIFF'S MEMORANDUM OF LAW
IN OPPOSITION TO DEFENDANTS' MOTION FOR
LEAVE TO AMEND ANSWER AND COUNTERCLAIMS**

DILWORTH PAXSON LLP

99 Park Avenue, Suite 320
New York, NY 10016
(917) 675-4260 (telephone)
(212) 208-6874 (facsimile)
jckessler@dilworthlaw.com

Attorneys for Harvey H. Jay, M.D.

PRELIMINARY STATEMENT

The Court should deny Defendants' belated attempt to amend their answer and counterclaims to include an inequitable conduct defense. [Dkt. No. 96] In their briefing, Defendants inexplicably apply the liberal standard for amendment of pleadings described by Federal Rules of Civil Procedure ("Rule") 15(a)(2), rather than the proper standard of Rule 16(b)(4). Because Defendants' Motion attempts to amend their answer well past the deadline for the amendment of pleadings, the more stringent "good cause" standard of Rule 16(b) applies. Applying the proper standard, it is clear that Defendants cannot meet their burden of showing "good cause" for adding their new defense because: (1) it is based almost exclusively on information contained in documents that have long been in Defendants' possession, and (2) the only "new" information proffered by Defendants to justify their late amendment is a blatant misquotation and misrepresentation of Dr. Jay's deposition testimony. For these reasons, and the reasons detailed below, Plaintiff respectfully requests that the Court deny Defendants' Motion in its entirety.

ARGUMENT

I. Defendants Apply The Wrong Legal Standard

Defendants advance the wrong legal standard in order to justify their belated Motion to Amend. Defendants cite to Rule 15(a)(2) for the proposition that, "[l]eave to amend [the pleadings] should be granted freely when justice so requires." *See* Defendants' Memorandum of Law [Dkt. No. 97] ("Memo"), at p. 2. Defendants also assert that, "[t]he only alleged basis given by Jay for opposing an amendment...is alleged 'undue delay.'" [*Id.*] Further, Defendants state that, "Jay has refused to consent to the amendment, asserting alleged delay but claiming no unfair prejudice from it or inadequacy of pleading." [*Id.*]

However, where, as here, a scheduling order governs amendments to the pleadings, *see* Rule 16(b)(4) (“[a] schedule may be modified only for good cause and with the judge’s consent”), “the lenient standard under Rule 15(a), which provides leave to amend ‘shall be freely given,’ must be balanced against the requirement under Rule 16(b) that the Court’s scheduling order ‘shall not be modified except upon a showing of good cause.’” *Holmes v. Grubman*, 568 F.3d 329, 334-35 (2d Cir. 2009) (quoting older versions of Rules 15(a) and 16(b)); *see also*, *Cordance Corp. v. Amazon.com, Inc.*, 255 F.R.D. 366, 371 (D. Del. 2009) (noting that “[m]otions to amend which, in effect, operate to change the scheduling order, are controlled by the rule governing modification to the court’s scheduling order, which applies a more stringent standard than a motion to amend and requires a showing of good cause by the movant and consent of the judge.”). Indeed, the more stringent “good cause” standard is explicitly referenced in the Court’s Pre-Trial Scheduling Order. *See* Pre-Trial Scheduling Order [Dkt. No. 23] at § 11 (“[t]he deadlines set forth in this Pre-Trial Scheduling Order will not be adjourned except in the Court’s discretion upon good cause as shown in a written application signed by counsel, stating whether the other part(ies) consent, and served upon all parties. ‘Good cause,’ as used in this paragraph, does not include circumstances within the control of counsel or the client.”) (emphasis added).

“Whether good cause exists turns on the ‘diligence of the moving party.’” *Holmes*, 568 F.3d at 335 (quoting *Grochowski v. Phoenix Constr.*, 318 F.3d 80, 86 (2003)). Specifically, “[t]he good cause element requires the movant to demonstrate that, despite diligence, the proposed claims could not have been reasonably sought in a timely manner.” *Cordance Corp.*, 255 F.R.D. at 371. Thus, “in contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party.” *Id.*; *see also*,

e.g., *Pressure Products Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308 (Fed. Cir. 2010) (“[f]or post-deadline amendments, a party “must show good cause for not meeting the deadline before the more liberal standard of Rule 15(a) will apply”); *Parker v. Columbia Pictures Indus.*, 204 F.3d 326, 340 (2d Cir. 2000) (“a district court does not abuse its discretion in denying leave to amend the pleadings after the deadline set in the scheduling order where the moving party has failed to establish good cause.”).

II. Defendants Have Failed to Establish “Good Cause”

In this case, whether “good cause” exists to justify Defendants’ failure to timely amend their Answer boils down to the following question: when were Defendants capable of *pleading* (as opposed to proving) the circumstances of inequitable conduct under Rule 9(b)? As one court has noted, “[o]f course, the standard for proving inequitable conduct is a more rigorous one than the standard for pleading inequitable conduct.” *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, No. CIV. 11-54-SLR, 2013 WL 571801, at *2 (D. Del. Feb. 13, 2013); *see also, Star Scientific, Inc., v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008) (stating that, [i]n contrast to the pleading stage, to prevail on the merits, the accused infringer must prove both materiality and intent by clear and convincing evidence”).

“To *plead* the ‘circumstances’ of inequitable conduct with the requisite ‘particularity’ under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009) (emphasis added). “Moreover, although ‘knowledge’ and ‘intent’ may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of

the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Id.*

Here, Defendants assert that, “Spectrum’s inequitable conduct defense concerns facts that always have been within Jay’s exclusive possession: whether Jay made representations to the PTO that he regarded as false based on his own prior art publications that he concealed from the PTO.” [Memo., at p. 5] Thus, Defendants assert that they were not capable of *pleading* the alleged circumstances of inequitable conduct until after they had taken Jay’s Deposition, purportedly because Jay’s deposition testimony “was required to confirm the propriety of raising that defense in this case.” [*Id.*] That is false, for at least two (2) reasons.

First, Defendants’ newly raised defense is based almost exclusively on information contained in documents that have been in Defendants’ possession since, at the very latest, September 10, 2014. *See* Declaration of Martin Gilmore [Dkt. No. 98] (“Gilmore Dec.”), at Exh. “D” (printout from Jay’s website obtained by Defendants on May 27, 2014); *id.*, Exh. “E” (article by Dr. Jay produced to Defendants on or about September 10, 2014); *id.*, at Exh. “F” (Patent Application Amendment, dated July 12, 2004, produced and/or obtained by Defendants around (or before) September 10, 2014). In fact, the only newer information relied upon by Defendants in support of their Motion is a single (misquoted) statement from Dr. Jay’s June 9, 2015 deposition (addressed below).

Further evidence that Defendants already possessed the information they purportedly needed to timely assert their inequitable conduct defense is found in the allegations made by Defendants in an email to Plaintiff’s counsel on March 5, 2014. *See* Gilmore Dec, at Exh. “I” (e-mail stating that, based upon Defendants’ review of Dr. Jay’s article titled “A Guide to Laser or Pulsed Hair Removal,” “[Defendants] have been disturbed to learn that Dr. Jay was aware of

significant prior art [referring to publication at Gilmore Dec. Exh. “E”] that he never disclosed to the PTO during the prosecution of his patents”).

Defendants have made no attempt in their Memorandum to explain why taking Dr. Jay’s deposition was necessary to enable them to satisfy the pleading requirements of Rule 9(b), or, alternatively, what new information was learned during Dr. Jay’s deposition that was not already known to them. Defendants are unable to provide the Court with such an explanation because, as stated above, all of the material relied upon by Defendants in formulating their inequitable conduct defense was produced in discovery prior to the deadline to amend pleadings. *See Pfizer Inc. v. Sandoz Inc.*, No. CV 12-654-GMS/MPT, 2013 WL 5934635, at *4 (D. Del. Nov. 4, 2013) (“[t]he timing of defendant’s motion...strongly suggests the delay is improper [since] [d]efendant had the requisite documents in its possession, at the latest, within a few weeks of the deadline to amend pleadings.”).

The second reason why Defendants’ newly raised defense is untimely is because it relies upon a blatant misquotation and misrepresentation of Dr. Jay’s deposition testimony – the only “new” information proffered by Defendants to justify the late filing of their Motion to Amend. The only citation to Dr. Jay’s deposition transcript in Defendants’ Memorandum is on page 4, where Dr. Jay is quoted as having purportedly said, “[e]verything is for a limited period of time.” [Memo., at p. 4 (emphasis added)]. In their Memorandum, Defendants assert that this statement is an admission by Dr. Jay that, in Defendants’ words, “in the context of hair removal ‘[e]verything is for a limited period of time,’ i.e., ‘temporary,’ even so-called ‘permanent’ hair removal.” [Memo at p. 4]. However, Defendants both misquote and misrepresent the plain context of the deposition transcript.

In their Memorandum, Defendants add the word “for” to the statement that was actually spoken by Dr. Jay during his deposition: *i.e.*, “Everything is a limited period of time.” [Gilmore Dec., Exh. “G” at 71:7-8] The deposition transcript from which Dr. Jay’s misquoted statement was excerpted demonstrates that Defendants were asking about – and Dr. Jay was replying about – the meaning of the phrase “limited period of time.” The relevant portion of the transcript reads as follows (Dr. Jay’s quoted statement is highlighted):

Q. Two years is a limited period of time, correct?

A. It’s limited if you -- if you were to describe a hundred years as being longer term. But anything -- I mean, in terms of anything less than infinity is limited.

Q. 12 months is a limited period of time, correct?

A. **Everything is a limited period of time.**

[Gilmore Dec., Exh. “G” at 70:22-71:8] Dr. Jay’s meaning could not be plainer: any and every period of time (12 months, 2 years, 100 years) shorter than infinity is literally “a limited period of time.”

In addition to the specific misquotation evident from the portion of Dr. Jay’s testimony excerpted above, the broader context of the deposition transcript surrounding that excerpt demonstrates that Dr. Jay’s misquoted statement was also not made in the context suggested by Defendants. Specifically, Defendants assert that Dr. Jay’s misquoted statement amounted to an admission that “in the context of hair removal ‘[e]verything is for a limited period of time,’ *i.e.*, ‘temporary,’ even so-called ‘permanent’ hair removal.” [Memo at p. 4]. However, that interpretation completely ignores the context in which Dr. Jay’s excerpted testimony was given.

Immediately preceding and following the testimony excerpted above, Defendants’ counsel questioned Dr. Jay regarding the meaning of the word “permanent” as used in a January 1999 publication by Dr. Jay (included as Gilmore Dec., Exh. “D”). Defendants’ counsel

intimated that the publication indicated that Dr. Jay considered “permanent” to last for only a “limited period of time.” Contrary to the misrepresentation urged upon the Court by Defendants, Dr. Jay explained that the article distinguishes between literally “permanent” hair removal and a definition of “permanent” that the FDA permits companies to use upon demonstrating hair reduction that endures for a period of time selected by the FDA. This context is apparent from looking at the deposition testimony that brackets the testimony referenced above:

Q. The third page, the third paragraph on page 2 in Exhibit 3 says, “Use of the term ‘permanent’ is controversial. ‘Permanent’ to most people means forever. That is not the case with hair removal.” Do you see that?

A. Yes.

Q. Did you ever tell the patent office that permanent hair removal, as you use it, doesn’t really mean permanent?

A. I didn’t say that’s the way I use it. I said, and the point here, which is stated in the next line, is that “permanent,” according to the FDA definition, at that point, I said, lasting for approximately two years. The current term for “permanent” is -- permanent hair reduction is a reduction lasting 12 months after treatment. That is the way “permanent” is defined by -- is used by the FDA. I didn’t say that was my decision.

Q. Do you believe that permanent hair removal lasts for a limited period of time?

A. Temporary hair removal lasts for a limited period of time. “Permanent” hair removal is a controversial term, just like I said here. I spelled it incorrectly but I meant controversial. Permanent hair removal is controversial. At that point it still is today. It is not a clearly defined term. “Temporary” is hair removal that lasts for a limited period of time.

Q. In Exhibit 3, you say, “‘Permanent’ meaning that hair removal lasted for approximately two years,” correct?

A. I’m looking for the spot. The sentence, the entire sentence says, “One ruby laser manufacturer recently obtained FDA permission to say ‘permanent,’ meaning that hair removal lasted for approximately two years.” That is what they received permission from the FDA to say based on the FDA’s analysis at that time. And as I just told you, that has [--. It’s] now one year,

12 months after treatment, and it's a reduction -- it's a stable [r]eduction.

[Gilmore Dec., Exh. "G" at 68:17-70:21; bracketed changes represent errata identified by Dr. Jay] The text referenced above occurs here and is omitted for brevity. The transcript then continues as follows:

Q. So, well, then permanent hair removal only lasts for a limited period of time, correct?

A. Well, people die. So in terms of permanent, the definition is more philosophical, and that's why it's a very difficult term to define. People die. Was their hair removal permanent? I guess you could say that [i]f you're defining it in terms of lifetime[. T]he definition to the FDA is some arbitrary decision that they made. Someone could define "permanent" as lasting different periods of time. I think "temporary" means for [a] limited period of time. So for that definition, you could say that permanent is not for a limited period of time.

Q. Dr. Jay, you say here, "Permanently removed hair will grow back," correct?

A. Permanent as according to the FDA's definition of permanent, which is one year. So therefore anything after one year, according to the FDA, would still qualify as permanent. And if it grew back, that would still be considered permanent hair [reduction]. That isn't my definition. That's the FDA's definition.

Q. Your definition of temporary is lasting for a limited period of time, correct?

A. No. That's the court's definition of temporary, according to our patents after the Markman hearing.

[Gilmore Dec., Exh. G at 71:9-72:19; bracketed changes represent errata identified by Dr. Jay].

The preceding passages – which surround the statement by Dr. Jay that Defendants misquote – plainly illustrate that Dr. Jay was attempting to distinguish the specialized term "permanent hair reduction" (which is a phrase that the FDA permits companies to use under certain circumstances defined by the FDA) from the term "temporary hair removal" (which is the phrase used in Dr. Jay's patents).

In its role as the federal regulator of marketing claims made for hair removal devices, the FDA distinguishes the terms “permanent reduction” and “permanent removal” of hair.¹ That is, “permanent hair reduction” and “permanent hair removal” are different phenomena. The FDA permits a company to claim “permanent hair reduction” if the company can demonstrate that use of its device results in a reduction in the number of countable hairs that lasts for at least 12 months after treatment, regardless of whether permanent hair removal, temporary hair removal, or a combination of permanent and temporary hair removal occurs. Dr. Jay’s patented methods recite “temporary hair removal.” In his deposition testimony reproduced above, Dr. Jay emphasizes the difference between hair reduction and hair removal. No reasonable interpretation of the portions of the deposition transcript, including the statement misquoted by the Defendants, supports Defendants’ assertion that Dr. Jay admitted that permanent hair removal endures for only a limited period of time. Thus, Defendants’ description of Dr. Jay’s testimony as effectively admitting that permanent hair removal, “is for a limited period of time” [Memo, at p. 4], simply mischaracterizes that testimony.

Defendants’ insertion of the word “for” into Dr. Jay’s statement (“Everything is a limited period of time”) and Defendants’ subsequent assertions that Dr. Jay’s misquoted statement was intended to mean that “permanent” hair removal is equivalent to “temporary” hair removal, appear to be deliberate attempts by Defendants to deceive the Court into misreading and misinterpreting Dr. Jay’s deposition testimony. However, Defendants’ misquotation and

¹ On its website, the FDA explains “Several manufacturers received FDA permission to claim, ‘permanent reduction,’ NOT ‘permanent removal’ for their lasers. This means that although laser treatments with these devices will permanently reduce the total number of body hairs, they will not result in a permanent removal of all hair.” <http://www.fda.gov/Radiation-EmittingProducts/ResourcesforYouRadiationEmittingProducts/ucm252761.htm>. This difference was also highlighted by Dr. Jay in his deposition testimony: “The term ‘reduction’ is different as defined by the FDA than the term ‘removal.’” Gilmore Dec., Exh. G at 73:20-25.

misinterpretation fail to establish “good cause” for Defendants’ substantial delay in filing their Motion to Amend.

Moreover, Defendants have not (and cannot) explain their substantial delay after receiving Dr. Jay’s written discovery until they filed the present Motion. Therefore, Defendants have failed to show “good cause,” and their Motion to Amend should be denied.

CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that the Court deny Defendants’ Motion to Amend in its entirety.

Dated: August 10, 2015
New York, NY

Respectfully submitted,

DILWORTH PAXSON LLP

By: /s/ John C. Kessler
John C. Kessler

John C. Kessler
99 Park Avenue, Suite 320
New York, NY 10016
(917) 675-4260 (telephone)
(212) 208-6874 (facsimile)
jckessler@dilworthlaw.com

Gary D. Colby
1500 Market St. 3500E
Philadelphia, PA 19102
(215) 575-7000 (telephone)
(215) 557-7200 (facsimile)
gcolby@dilworthlaw.com

James J. Rodgers
1500 Market St. 3500E
Philadelphia, PA 19102
(215) 575-7000 (telephone)
(215) 557-7200 (facsimile)
jrodgers@dilworthlaw.com

Attorneys for Harvey H. Jay, M.D.

CERTIFICATE OF SERVICE

I, John C. Kessler, Esq., hereby certify that, on August 10, 2015, the foregoing Memorandum of Law in Opposition to Defendants' Motion for Leave to Amend Answer and Counterclaims was served upon all parties of record via the Court's ECF system

/s/ John C. Kessler